DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 1999

Office of the Secretary,
Federal Communications Commission
The Portals, Room TW-A325
445 12th Street, S.W.
Washington, D.C. 20554

Dear Secretary Salas:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration strongly supports the FCC proposal (ET docket 99-255) establishing a Wireless Medical Telemetry Service (WMTS) to reduce the risk of electromagnetic interference (EMI) with vital patient signals. This proposal addresses the clear need to resolve the potential problems of EMI with wireless medical telemetry. The proposed new spectrum, with primary status for WMTS, coupled with a Frequency Coordinator whose function is to facilitate coordinated WMTS use and new equipment information, should provide increased protection for wireless medical telemetry and the public health.

We have reviewed the NPRM for establishing the WMTS and have a number of specific comments (see attachment) that we would like to bring to FCC's attention. Chief among these is our concern about auction for the WMTS spectrum and concern about the potential overlap of the little LEO system. We also comment on the voluntary requirements for WMTS equipment labeling and the lack of some important information to be provided for this equipment. We very much support the establishment of a Frequency Coordinator, and suggest that the functions and duties of the Coordinator be better described, especially in the use of the information collected toward avoiding potential EMI situations. In light of the large installed base of medical telemetry, the limited resources available to the healthcare users, and the potential public health impact of electromagnetic interference with vital patient signals, we believe that the concerns expressed by the American Hospital Association (AHA) for the transition to the new spectrum should be given priority.

CDRH applauds the FCC for the important steps it is taking to protect the public health by providing increased protection for wireless medical telemetry. We firmly believe that

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interference-free monitoring of patients by means of biomedical telemetry is essential to the safety and effectiveness of many medical devices. We look forward to continuing cooperation with the FCC to see that our common goals for a WMTS are brought to fruition.

Sincerely yours,

Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and
Radiological Health

Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) Comments on FCC NPRM (ET Docket 99-255) for Wireless Medical Telemetry

General comments

In general, CDRH, FDA applauds FCC's efforts to create separate spectrum for wireless medical telemetry. We agree that wireless medical telemetry needs its own spectrum and use rules so that the risks to patients resulting from electromagnetic interference (EMI) with medical telemetry will be minimized.

We have several specific concerns and comments from our review of the Notice for Proposed Rule Making (ET Docket 99-255). Our major concerns lay with the proposals for use of the spectrum, transition period, equipment labeling, and frequency coordination. We participated in the AHA Wireless Medical Telemetry task group and believe these recommendations represent a balanced consensus for solutions to reduce the risks represented by wireless medical telemetry EMI. Although the NRPM makes it clear that the AHA recommendations formed the basic proposal for WMTS, there are some differences that raise concerns about the effective use and coordination of the new service.

In addition, we would like to comment on the issue of auction of the proposed spectrum for WMTS. From our perspective, the public health impact of the WMTS clearly outweighs any potential benefits of an auction. Further, any overlap of the WMTS with the frequency spectrum allocated to "little" Low Earth Orbiting (LEO) satellite systems would seem to compromise the intended purpose of the WMTS to reduce the potential for EMI with medical telemetry.

Finally, we believe that WMTS equipment and devices should be required to be clearly labeled with basic operating information, so that present and future users can easily and quickly coordinate device use. The FCC proposal to allow manufacturer discretion to supply such information in a voluntary approach may not result in the desired frequency coordination.

Specific comments are detailed below.

Specific Comments

1. Section A. 1., paragraph 12. CDRH supports the findings of the AHA Task Group on medical telemetry. There is presently a need for at least 6 MHz of spectrum, with a future need of at least 12 MHz of spectrum. It is likely that the use of medical telemetry will become more widespread, driven by medical care cost factors and increasing advances in medical device technology.

2. Section A.2., paragraph 13. CDRH has consistently supported primary status for medical telemetry. Since most of the installed base of devices operates in either the PLMRS or TV bands it makes sense to allow part of the WMTS to operate within the capabilities of some of the present equipment. The allowance for use of TV channel 37 (608-614 MHz) is a reasonable compromise. The addition of spectrum above 1 GHz poses a challenge for the manufacturers and users, since only a small portion of the current medical telemetry devices

are capable of operating above a few hundred megahertz. Members of the AHA Task group from the manufacturing community have supported the allocation of spectrum in the general frequency ranges proposed by FCC; however, CDRH is concerned about capabilities of both the manufacturers and clinical users to make the transition to the new spectrum in the time frame proposed by FCC (as noted below in comment 14).

3. Paragraph 17. CDRH is concerned that auction of the new spectrum has been proposed as an option. Hospitals, users, and telemetry manufacturers have made it clear that they cannot afford to purchase spectrum for wireless medical telemetry, and no industry-wide consortium exists that has the financial means to purchase the needed spectrum. In our view, the potential public health benefits far outweigh any commercial benefit offered by the auction process. Further, an auction of the spectrum for WMTS might further delay the establishment of a WMTS for reducing the risk of patient safety consequences through reduced EMI. Therefore, CDRH suggests the free allocation of a portion of the spectrum for wireless medical telemetry to protect public health and safety.

4. Paragraph 21. CDRH is concerned about co-primary status in the identified WMTS frequency spectrum for the little LEO systems. The fundamental purpose for the WMTS is to reduce the potential for EMI with other signals and give medical telemetry a primary status in separate spectrum. With the wide geographic dispersion of medical telemetry use facilities, and the possibility of signal overlap resulting in EMI to the medical telemetry, the public health risks to WMTS outweigh any commercial benefits for little LEOs. While CDRH takes a neutral stance about the 2 options for spectrum, we support the recommendations of the AHA Medical Telemetry task group for allocation of spectrum. This includes the use of two-way communications between the monitoring station and the patient-mounted device.

5. Section B. paragraph 28. CDRH agrees with the definition of wireless medical telemetry as stated in paragraph 25. However, the general trend in healthcare is toward more use of medical devices for out-patient care and particularly in-home care. There are a number of home use, telemetry-type systems in use today that link to the clinician via telephone communications. It is conceivable that the WMTS might be useful for medical devices that are designed to go into the home, perhaps with a central communications link via the telephone. The control of wireless medical telemetry use for avoiding potential EMI is a primary concern, but there should be some allowance for growth in the use of this service. Thus, CDRH suggests the addition of text stating that future consideration will be given to the use of WMTS in non-traditional health-care settings, such as the home.

6. Paragraph 29, Frequency Coordination. CDRH strongly supports the appointment of a "Frequency Coordinator" whose primary functions will be to maintain databases of WMTS users to avoid interference among users, coordinate with other spectrum users (including government and military), and promote the safe and effective use of the WMTS. The Frequency Coordinator should proactively intercede to avoid interference between users during the filing stage of the user's intended spectrum use. The Frequency Coordinator should also be free to inform the potential new user applicant of unused spectrum available in the given geographic area. Also, manufacturers of the WMTS equipment should be strongly

encouraged (if not required) to support the filing institution in the application process with the Frequency Coordinator.

7. Paragraph 30. As to the qualifications for the Coordinator and the coordination process, our general view is that the Coordinator should be familiar with medical telemetry and with types and functions of equipment in the clinical/hospital environment. The Coordinator could thus appreciate the various situations and needs that arise in the clinical environment. A single Coordinator would have the advantage of a central repository for the telemetry information, but a well controlled multiple entity may also be viable. Comments on this aspect from the clinical community should be given the highest weight. For the coordination of WMTS to work effectively, the widest possible participation of healthcare facilities is essential. Thus, the fees charged by the Coordinator should be minimal, and have less impact on those facilities with smaller use of wireless medical telemetry.

8. Paragraph 31. The information gathered by the Frequency Coordinator should also include makes and model numbers of the equipment using the WMTS. This information would be useful in order to facilitate solutions in case there were incidents of device disruption. Further, the regulatory description of this information should be more specific, since the general intention of gathering the database information is to avoid possible EMI conflicts, and specific information makes this process much easier. For example, information on radiated power must include the make and model of the device that transmits this energy. Similarly, the address and general telephone number of the healthcare facility must be included. To facilitate communications, user contact information in the database should also include a fax number and an electronic mail address.

9. Paragraph 32. The primary use of the database frequency coordination information is to avoid potential EMI situations where possible, provide tracking of the use of WMTS devices to help resolve conflicts or trace potential problems, and help to monitor general trends in the use of WMTS. Thus, this information should be restricted to those parties with needs for the information that are directly related to healthcare and to government agencies with appropriate regulatory authority.

10. Paragraph 33. CDRH agrees that the primary use of the WMTS should be for the transmission of vital patient information. FCC expresses a valid concern that voice or video applications of the WMTS might lead to spectrum congestion impeding vital patient data communications. However, there are distinct advantages in allowing WMTS to expand capabilities of the technology into areas such as audio and medical images. For example, it is conceivable that the technology for vital ambulatory patient data (such as physiological images representing data from many patient sensors) or direct patient communications could become viable in spectrally efficient ways that would augment the medical capabilities of WMTS. There may be alternative forms of wireless communication for audio and medical image information, however, it must be noted that these would introduce additional transmissions into the healthcare environments where there are many potentially EMI susceptible critical medical devices. Thus, the introduction of potentially viable technologies for the communication of patient information should not be specifically precluded from the WMTS. FCC should consider modifications to the text of the proposed rule that allows for

such technology if these can be made sufficiently narrow in spectrum use so as to not hinder effective use of the WMTS by all appropriate users.

11. Paragraph 35. CDRH supports the recommendation of the AHA Telemetry task group to allow for the widest possible use of the WMTS.

12. Paragraph 38, Protection of other existing services. It is clear that the WMTS will have to coordinate use with the radio astronomy community in the Channel 37 band, and certain government users in approximately the 1391 MHz frequency range. This coordination should be made a fundamental part of the Frequency Coordinator's function. The Coordinator should also provide a clearinghouse of information on potential EMI, and should be responsible for making sure that each facility using the WMTS is aware, and has taken the proper precautions, not to interfere with either astronomers or government users. Such responsibilities are consistent with the primary functions of the Coordinator, who will have the needed information for these functions. Additionally, the Frequency Coordinator should act to coordinate with the local and federal government spectrum users so that in the event of any required government transmissions in the WMTS spectrum (e.g., declared emergency) within the affected area the WMTS Coordinator would notify affected WMTS users about the impending WMTS takeover. In such an event, the Frequency Coordinator's role is vital to accommodate the temporary government use of the WMTS while maintaining coordination for patient safety. The Coordinator might be able to transition users to an alternate portion of the WMTS spectrum.

13. Paragraph 39, Equipment authorization requirements. CDRH supports the original AHA recommendations for additional information from the device manufacturer, including the operating frequencies, modulation scheme, radiated power, and Frequency Coordinator contact information. As stated in Paragraph 31 this information is needed by the Coordinator and should be readily available to the purchaser and any subsequent equipment user. Thus, we would support a mandatory requirement for the basic information recommended by the AHA task group for WMTS devices and equipment information. Because the typical use life of medical telemetry devices can be 10 years or more (from the 1998 ASHE survey of telemetry users), we also recommend that a summary of this information be permanently affixed to the WMTS equipment.

    In addition, there is a market for resale or refurbishment of medical telemetry devices, where original information is likely to be separated from the equipment, further reducing the effectiveness of voluntary disclosure of critical device information. As with the original equipment manufacturers, WMTS equipment resellers and refurbishers should be required to provide the same information as the original equipment manufacturer. Further, the reseller should be strongly encouraged (if not required) to aid the purchaser in the application process with the Frequency Coordinator.

14. Paragraph 41, Transition Provisions. CDRH supports the original recommendations of the AHA Telemetry task group for a 4 year transition to the new WMTS. This has also been echoed by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in its most recent public meeting with CDRH. Healthcare facilities and

manufacturers should be encouraged to design and use new devices operating in the WMTS spectrum, but they should also be allowed adequate time to make the transition in an orderly manner.

For its part, CDRH has continuously worked with the FCC, AHA, and device manufacturers to keep all manufacturers abreast of the developments and recommendations. CDRH has sent letters to the device manufacturers relating information about these developments, and has been developing its own regulatory guidance for manufacturers to help them determine the most expeditious regulatory process. With the large installed base of equipment in use, manufacturers and users of wireless medical telemetry need to be aware of the risks involved in continuing to use the Part 15 and 90 spectrum. The choice to accept these risks should be made by the healthcare facility based upon its particular circumstances and needs.